# Can We reduce Fetal Loss with Second Trimester Miscarriages and very Preterm Births due to Cervical Incompetence in Women with Repeated Failed Vaginal Cerclages and/or Inaccessible Cervices?

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#### ABSTRACT

**Objective:** To assess the reduction in fetal loss following transabdominal cervicoisthmic cerclage done for repeated failed vaginal cerclages and/or inaccessible cervices.

**Study design:** An observational study of 113 pregnancies in 90 women after transabdominal cervicoisthmic cerclage from January 1999 to December 2010 at Fernandez Hospital, Hyderabad, Andhra Pradesh, India.

Results: Mean gestational age at the time of elective transabdominal cervicoisthmic cerclage was 11.6 weeks. Patients were delivered by lower segment cesarean section (LSCS) with a mean gestational age of 36 weeks. Live birth rate was 90.5%. Incidence of mid-trimester miscarriages was 8.6% after cerclage compared with 62.9% before cerclage. Before cerclage, only 13.1% pregnancies continued beyond 28 weeks whereas after cerclage, 88.6% crossed the period of viability. Prior to cerclage, preterm delivery rate was 7.0% (as majority of the pregnancies were lost prior to period of clinical viability) and only 13.6% of these preterm babies survived. Although the incidence of preterm deliveries was 23.8% after cerclage, 80% of these preterm babies survived. Excluding first-trimester miscarriages, fetal loss was 93.3% prior to cerclage and 13.7% postcerclage. In effect, the take home baby rate among pregnancies was only 5.8% before cerclage compared with 86.7% after cerclage. Mean birth weight after cerclage was 2.5 kg.

**Conclusion:** Transabdominal cerclage reduces fetal loss and improves pregnancy outcome in women who had failed vaginal cerclages and in those with inaccessible cervices.

**Keywords:** Transabdominal cervicoisthmic cerclage, Transvaginal cerclage, Cervical incompetence.

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#### INTRODUCTION

Cervical insufficiency is defined as the failure of the cervix to retain an intrauterine pregnancy until term. The classic

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clinical history is a recurrent second or early third-trimester fetal losses characterized by painless dilatation of the cervix followed by prolapse and rupture of the membranes and expulsion with minimal uterine activity of a usually live fetus.<sup>1</sup> The diagnosis is usually made in retrospect, based on the clinical history and after exclusion of possible causes of preterm uterine activity. Previous reports suggest that about 1% of all pregnant women and 8% of women who suffered second or early third-trimester losses could be affected.<sup>2</sup> Loss of cervical integrity due to surgery or trauma and functional impairment associated with exposure to diethylstilbestrol (DES) *in utero* are recognized as important risk factors.<sup>3,4</sup>

Surgical treatment of cervical insufficiency consists of cervical cerclage in a subsequent pregnancy although the benefit of the procedure is disputed.<sup>2</sup> Approximately 13% of women with cervical incompetence will not be successfully treated with a transvaginal cerclage and will deliver previable infants despite this intervention.<sup>5</sup> Contraindications to the vaginal approach include an absent, very short, or severely lacerated intravaginal portion of the cervix as a result of developmental abnormality, previous surgery or failed transvaginal cerclage. In these women, transabdominal cervicoisthmic cerclage, as first described by Benson and Durfee,<sup>6</sup> may be the only possibility for prophylactic or therapeutic surgical closure of the insufficient cervix.

# MATERIALS AND METHODS

We studied a total of 90 women who underwent transabdominal cervicoisthmic cerclage between January 1999 and December 2010 in the Department of Gynecology at Fernandez Hospital, Hyderabad, Andhra Pradesh, India. Selection for transabdominal cervicoisthmic cerclage was based on the following criteria:

- 1. A classic history of cervical insufficiency<sup>1</sup> and/or
- 2. A cervix that precluded the effective placement of a transvaginal cerclage. Cervices that precluded transvaginal cerclage were extremely short, with a vaginal portion of less than 2 mm, had deeply notched multiple defects or a combination of these factors. Other

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potential causes of second or early third-trimester pregnancy losses, such as maternal endocrine, systemic or autoimmune disorders, isoimmunization, chronic cervical infections were investigated.

We aimed at performing primary transabdominal cerclage at the end of the first-trimester of pregnancy. Gestational age, fetal cardiac activity and the absence of detectable fetal anomalies were ascertained by nuchal transluscency scan. None of the patients had experienced abnormal uterine contractility, ruptured membranes or uterine bleeding before surgery. Ultrasound measurement of cervical length before the transabdominal cerclage was routinely performed. Detailed preprocedure counseling was done about the procedure, related complications, need for two laparotomies [cerclage and lower segment cesarian section (LSCS) at 36 weeks], possible complications leading to fetal demise, mode of delivery in case of fetal demise and cerclage tape removal.

All transabdominal cervicoisthmic cerclage procedures were performed by investigators LR or SD using the technique reported by Benson and Durfee.<sup>6</sup> Under general or epidural anesthesia, the peritoneal cavity was entered by a Pfannenstiel incision. The uterovesical fold of peritoneum was opened and the bladder was advanced downward to expose the cervicoisthmic junction. Very gently, the uterus was exteriorized. The avascular area between the pulsating ascending and descending branches of the uterine artery and the lateral border of the uterus at the isthmus was identified by palpation on both sides. One hand was placed behind the gravid uterus and the uterine vasculature was gently displaced laterally guided by a posterior finger. A 30 cm long, 5 mm wide mersilene tape with a swaged needle (RS 21 with blunt tip; Ethicon) was used for the procedure. The anterior leaf of broad ligament was pierced with the blunt needle and the tape was gently pulled through the paracervical space from anterior to posterior. The procedure was repeated on the other side. The tape was pulled tight around the cervix, and the ascending branches of the uterine arteries were palpated to confirm the presence of pulsations. The tape was then tied snugly on the posterior aspect of the cervix and the cut ends were fixed with 2-0 chromic catgut absorbable sutures. Anteriorly, the uterovesical fold of peritoneum was closed over the tape. Posteriorly, the tape was left uncovered by peritoneum. The uterus was kept moist throughout the procedure. Prophylactic antibiotics were administered as a routine to all women.

All patients received routine postoperative care and were usually discharged within 4 days. Standard antenatal care was provided with routine fetal surveillance. Vaginal or ultrasound examinations of the cervix were not routinely performed. Reduction of physical and sexual activity was recommended to all. Our intention was to perform an elective cesarean delivery by a transverse uterine incision above the level of the tape between 36 and 38 weeks of gestation and to leave the mersilene tape *in situ*. The tape was removed when the patient completed her family. In a few instances, like late miscarriages due to noncervical reasons when the patient decided to get the tape removed, it was done through colpotomy. In the above circumstances, if the patient wished to retain the tape, hysterotomy was performed.

All data concerning patient's history, surgery, course of pregnancy, delivery, postpartum period and follow-up were recorded as part of a standardized protocol over the period of 10 years. To ascertain completeness of follow-up, we reviewed all files of women who had remained in our care. For this study, we analyzed the data concerning the index pregnancy, in which transabdominal cervicoisthmic cerclage was performed and also the subsequent pregnancies with cerclage *in situ*.

## RESULTS

A total of 90 women underwent placement of transabdominal cervicoisthmic cerclage. Of these, 84 women (93.3%) underwent the procedure during pregnancy whereas six had an interval procedure in the nonpregnant state. Four of the interval procedures were performed laparoscopically. Majority (42.6%) of the patients were between 26 and 30 years of age (Table 1).

Indications for transabdominal cervicoisthmic cerclage were failed transvaginal cerclage(s) in 69 (76.7%) women and inaccessible cervices in 21 (23.3%) women. Twentyfive out of the former (36.2%) had two or more failed transvaginal cerclages. Of the latter, five women had very short cervices associated with uterine anomalies and another five women had traumatized cervices. A total of 17 uterine anomalies had been detected by hysteroscopy in the preoperative evaluation of recurrent pregnancy losses. Twenty-two women (26.2%) of the study population were in their fourth pregnancy. The obstetric history of the women is summarized in Table 2.

Outcomes after cerclage were significantly (paired t-test p-values <0.001) better compared to the precerclage history

Table 1: Details of the 90 women included in the study			
Mean age of patients	28.1 years		
Total no. of patients (procedures) No. of interval cerclages Total no. of pregnancies Lost to follow-up Ongoing pregnancies No. of women who did not conceive yet	90 6 (6.7%) 113 4 4 2		

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Table 2: Precerclage obstetric history					
Variables	Number	Percentage			
No. of previous pregnancies First-trimester miscarriages Second-trimester miscarriages Third-trimester births	313 75 197 41	- 24 62.9 13.1			

for the same women (Table 3). The gestational age following transabdominal cervicoisthmic cerclage was advanced to 34 weeks and beyond in 78.1% and to 37 weeks and beyond in 64.8% whereas prior to cerclage, only 6.1% of pregnancies continued beyond 37 weeks.

The primary outcome analyzed was delivery of a live baby after period of clinical viability (28 weeks of gestation). Of the 105 pregnancies analyzed, 93 continued beyond 28 weeks. There was one intrauterine fetal death at 32 weeks and 92 pregnancies resulted in live births. There were three sets of twins, the total number of live babies added up to 95. Four babies succumbed in the neonatal period.

Mersilene tape was removed by colpotomy in five cases; three women had missed miscarriages and two had preterm premature rupture of membranes.

When reviewing the fetal losses, a complication of particular interest was fetal loss related to the procedure because only patients who were pregnant at the time of cerclage placement could have a loss related to the procedure. We arbitrarily defined losses that occurred within 2 weeks of the procedure as procedure-related fetal losses. There were two procedure-related fetal losses in this series. One patient with unicornuate uterus and twin pregnancy miscarried on the day of surgery. The other patient had rupture of membranes in the immediate postoperative period and the mersilene tape was removed through colpotomy.

Four patients had congenital anomalies of the fetus detected at a later date—renal agenesis, polydactyly, Hirschsprung's disease and valgus deformity of foot. The woman with renal agenesis wished to continue the pregnancy despite counseling about the lethal nature of the anomaly. Intrauterine fetal demise was detected at 32 weeks on routine antenatal checkup in another patient with uterus didelphys who had mild pre-eclampsia.

#### DISCUSSION

Transabdominal cervicoisthmic cerclage procedure for cervical insufficiency is generally limited to those women with a cervix that is too short or scarred for a traditional transvaginal cerclage. It can also be considered in a case of failed transvaginal cerclage, if there are additional second trimester miscarriages or preterm births or if the cervix is too short/inaccessible.

The higher number of term and late third-trimester infants delivered after cerclage (compared with those before cerclage) strongly suggests benefits from transabdominal cervicoisthmic cerclage. Excluding first-trimester miscarriages, fetal loss was 93.3% prior to cerclage and 13.7% postcerclage. In effect, the take home baby rate among pregnancies before cerclage was only 5.8% compared to 86.7% after cerclage. Second-trimester losses were 8.6% after abdominal cerclage compared with 62.9% before cerclage.

We preferred to perform the procedure between 11 and 14 weeks as later in the second trimester, it becomes more difficult to obtain adequate exposure and manipulation of the larger uterus could lead to uterine contractions. There is no apparent indication to perform transabdominal cerclage before 12 weeks of gestation because it is unlikely that spontaneous abortions during that period are related to cervical insufficiency.

The retrospective design maybe considered a limitation although that is offset to a certain degree by the comparison with the precerclage history. The interval from which our retrospective cohort was gathered is long with numerous changes in neonatal care that culminated in improved survival. These improvements could have biased our results but as a matter of fact, the proportion of live babies delivered before 37 weeks who might have required neonatal care reduced from 53.8% before cerclage to 27.4% after cerclage. The decrease in preterm births may be considered a better measure of success as it avoids the neonatal intensive care unit stay for the baby and the associated financial burden apart from decreasing the associated problems of prematurity. A prospective randomized trial will provide the best level of evidence but has to be carefully planned as a multicenter trial to achieve required power.

Table 3: Pre- and postcomparison of outcomes after cerclage					
	Precerclage (no.)	Percentage	Postcerclage (no.)	Percentage	
Mid-trimester miscarriages	197/313	62.9	9/105	8.6	
Pregnancy beyond 28 weeks	41/313	13.1	93/105	88.6	
Preterm deliveries	22/313	7.0	25/105	23.8	
Total live births	39/313	12.5	95/105	90.5	
Total neonatal deaths	21/41	-	4/93	-	
Take home baby rate	18/313	5.8	91/105	86.7	

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The diagnosis of cervical insufficiency in these selected patients is supported by the finding that none of the subjects had true labor prior to 32 weeks after abdominal cervicoisthmic cerclage. The preterm delivery (<35 and <33 weeks of gestation) rates in our study were 13.3 and 8.6% respectively and lower than the results of Davis et al who reported 18 and 10% respectively.<sup>7</sup> They also reported that transabdominal cerclage was associated with a lower incidence of preterm rupture of membranes and preterm delivery compared with transvaginal cerclage. Our incidence of preterm rupture of membranes after 28 weeks of pregnancy was 5.7% after cerclage. Our results are comparable to that of Lotgering et al<sup>8</sup> who quoted 27.5% neonatal survival before cerclage and 93.5% after cerclage and Cammarano et al<sup>9</sup> who reported 18 and 93% pre- and postcerclage respectively. Excluding first-trimester miscarriages, fetal loss was 93.3% prior to cerclage and 13.7% postcerclage.

With recent evidence supporting the efficacy of the use of 17  $\alpha$ -hydroxy progesterone caproate to prevent recurrent preterm births, patients with a history of spontaneous preterm birth including those whose history is consistent with cervical insufficiency have been offered both transvaginal cerclage and progesterone in hope of achieving an improved pregnancy outcome.<sup>10</sup> In our study, we have not routinely administered progesterones and, hence, did not analyze any effects of progesterone. A prospective study that compares relative benefits of the administration of progesterone in this group is necessary.

Although the reported incidence of improved perinatal survival is higher,<sup>11</sup> there is a small risk of morbidity associated with this procedure. The maternal risk of transabdominal cervicoisthmic cerclage is bleeding from parametrial vessels as suture involves a highly vascular area. An extensive dissection at this area is not necessary and gentle lateral displacement of uterine vessels avoids the risk. After pulling the tape through, the uterine arteries should be palpated to make sure that they are not caught in the tape which can compromise the blood supply to the fetus severely. There were no serious complications, such as significant blood loss during the procedure requiring blood transfusion, damage to the surrounding viscera or prolonged hospital stay. Blood loss more than 500 ml was noted in three cases (2.9%) performed by Lotgering et al.<sup>8</sup> One woman in our study with continuous pyrexia was diagnosed to have tuberculous meningitis and was lost to follow-up.

The major objections for transabdominal cervicoisthmic cerclage are the need for two laparotomies and the risk of intraoperative blood loss from extremely vascular area at the isthmus. The transabdominal cervicoisthmic cerclage may be left in place for future pregnancies whereas a vaginal cerclage must be replaced. Earlier, blood loss was a problem; however, Novy describes an alternative technique of manual retraction of the uterine vessels and passage of suture in the clear space between the vessels and the uterine isthmus without tunneling. With this technique, hemorrhage can be avoided. The mersilene tape is not removed at cesarean section as it can serve for future pregnancies, which many patients desire after experiencing the successful outcome of the current pregnancy.

The lacerated, partially or completely absent intravaginal cervix is unfeasible for transvaginal cerclage. Other alternative approaches for such cervices are placement of transabdominal cervicoisthmic cerclage in nonpregnant state or Shirodkar cerclage during pregnancy.

#### CONCLUSION

With the results of our study, we conclude that the transabdominal cervicoisthmic cerclage offers a high rate of fetal salvage in patients with extremely poor obstetric histories as a result of cervical incompetence, where vaginal cerclage is not possible or has repeatedly failed. The risk of procedure-related complications can be minimal in skilled hands. It is a specialized procedure for selected patients in whom it improves the perinatal outcome. With the advent of advanced laparoscopic procedures, laparotomy for cervicoisthmic cerclage can be avoided.

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